



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

[Docket No. FDA-2011-N-0003]

New Animal Drugs; Change of Sponsor's Name

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name from Nycomed US, Inc., to Fougera Pharmaceuticals, Inc.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

Steven D. Vaughn,
Center for Veterinary Medicine (HFV-100),
Food and Drug Administration,
7520 Standish Pl.,
Rockville, MD 20855,
240-276-8300,
email: steven.vaughn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Nycomed US, Inc., 60 Baylis Rd., Melville, NY 11747 has informed FDA of a change of name to Fougera Pharmaceuticals, Inc. Accordingly, the Agency is amending the regulations in 21 CFR 510.600(c) to reflect these changes.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. In §510.600, in the table in paragraph (c)(1), remove the entry for “Nycomed US, Inc.”; alphabetically add a new entry for “Fougera Pharmaceuticals, Inc.”; and in the table in paragraph (c)(2), revise the entry for “025463”.

The addition and revision read as follows:

§510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Fougera Pharmaceuticals, Inc., P.O. Box 2006, 60 Baylis Rd., Melville, NY 11747	025463
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
025463	Fougera Pharmaceuticals, Inc., P.O. Box 2006, 60 Baylis Rd., Melville, NY 11747
* * * * *	

Dated: January 24, 2012.

William T. Flynn,

Acting Director,

Center for Veterinary Medicine.

[FR Doc. 2012-1756 Filed 01/26/2012 at 8:45 am; Publication Date: 01/27/2012]